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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,744	11/18/2003	Mark E. Fauver	60080US	6749
23-10, 7590 GEORGE A LEONE, SR CITADEL PATENT LAW			EXAMINER	
			WEATHERBY, ELLSWORTH	
1117 BROAD SUITE 401	WAY		ART UNIT	PAPER NUMBER
TACOMA, WA 98402			3768	
			MAIL DATE	DELIVERY MODE
			06/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/716,744 FAUVER ET AL. Office Action Summary Examiner Art Unit ELLSWORTH WEATHERBY 3768 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status Responsive to communication(s) filed on 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-55 is/are pending in the application. 4a) Of the above claim(s) 24-27 and 29-53 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-23.28.54 and 55 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 24-27 and 29-53 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)
 Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date See Continuation Sheet.

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/26/2005; 8/29/2005; 5/24/2007; 5/24/2007; 1/28/2008; 2/18/2009.

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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - Claims 1-23, 28 and 54-55 drawn to confocal imaging, classified in class 356, subclass 444.
 - Claims 24-27, drawn to sample handling, classified in class 73, subclass 863.
 - Claims 29-53, drawn to optical systems having piezoelectric optical modulation, classified in class 359, subclass 323.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because invention I is concerned with multi-dimensional imaging through the operation of the imager elements. The subcombination has separate utility such as use in any microscopy system.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all

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the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Invention I is merely concerned with performing imaging in a plurality of planes. The subcombination has separate utility such as optical coherence tomography.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such

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claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

- 4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:
 - (a) the inventions have acquired a separate status in the art in view of their different classification:
 - (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
 - (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
 - (d) the prior art applicable to one invention would not likely be applicable to another invention:
 - (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with George Leone (Reg. 30567) on 6/16/2009 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-23, 28 and 54-55. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-27 and 29-53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Claim Objections

Claim 24 is objected to because of the following informalities: Regarding claim
 applicant claims "said capillary...". This should read "said micro-capillary tube".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 17, 24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- Regarding claim 17, Applicant claims "moving an oil-immersion lens perpendicularly..". It is not clear to what axis or reference point that the oil-immersion lens is being moved perpendicularly.
- 10. Regarding claim 24, Applicant claims "allowing the micro-capillary tube to be rotated about its axis". The micro-capillary tube is a three-dimensional structure having a plurality of axes. Therefore, the claimed "it's axis" is interpreted by the examiner as meaning "it's longitudinal axis".
- 11. Regarding claim 27, Applicant claims "..in a direction perpendicular to a planar surface of the substrate". The substrate may have three-dimension forms thereby

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allowing any number directions that would be perpendicular to a planar surface of the substrate

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filled in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 35(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- Claims 1-3, 5-6, 8-10 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Ohyama et al. (USPN 5,680,484).
- 14. Ohyama et al. (hereinafter Ohyama) teaches a method for multi-dimensional imaging of a specimen region (col. 7, I. 45- col. 8, I. 22), comprising the steps of: acquiring images from a continuum of parallel focal planes either sequentially or continually, wherein each of the continuum of parallel focal planes is within a specimen region perpendicular to the incident light rays, such that a pseudo-projection is compiled (abstract; col. 8, II. 22-45; col. 10, II. 15-30); and repeating the above step for two or more view points about an arc at least partially encircling the specimen region for tomographic image reconstruction (abstract; col. 8, II. 27-45). Ohyama also teaches that the acquiring step is repeated about multiple arcs with common line or point of

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intersection at least partially encircling the specimen region for tomographic image reconstruction (col. 7, II. 5-44; col. 8, II. 16-56). Ohyama also teaches moving the focused surface of the objective lens along the length of a transparent specimen tube to acquire the continuum of parallel focal planes (col. 8, II. 20-25). Ohyama also teaches moving the objective lens relatively to the specimen region to acquire the continuum of parallel focal planes (col. 7, II. 33-44; ref. 913). Ohyama further teaches the step of imaging the continuum of parallel focal planes onto a two-dimensional array of detectors during a single integration interval of the two dimensional array of detectors (col. 6, II. 21-30; ref. 303). Ohyama also teaches that the specimen region comprises a cell (col. 7, II. 45-51).

Claim Rejections - 35 USC § 103

- 15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5,680,484) in view of Palcic et al. (USPN 6,026,174).
- 17. Ohyama teaches all the limitations of the claimed invention except for expressly teaching using a computer algorithm to extract features of interest from one or more of the images.

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18. In a related field of endeavor, Palcic et al. (hereinafter Palcic) teaches a computer controlled digital microscope (abstract; col. 2, II. 8-35). Palcic also teaches automated feature extraction using a computer and algorithm based image analysis (abstract; col. 2, I. 64- col. 3, I. 31).

- 19. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscope of Ohyama in view of the automated feature extraction of Palcic. The motivation to modify Ohyama in view of Palcic would have been to provide repeatable diagnosis using well known techniques, as taught by Palcic (col. 2, II. 8-35).
- Claims 7, 12-13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5,680,484) in view of Krantz (USPN 6,248,988).
- 21. The optical imaging microscopy of Ohyama teaches all the limitations of the claimed invention except for expressly teaching that the step of moving the optical element is accomplished by driving a piezoelectric element coupled to the optical element. Ohyama also does not expressly teach illumination the specimen with a laser or an incoherent light source. Ohyama also does not expressly teach a microlens array. Ohyama also does not expressly teach using a confocal arrangement with an extended lateral field of view.
- In a related field of endeavor, Krantz teaches a confocal optical tomography system employing multiple sets of pseudo-projection viewing subsystems (abstract; col.

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- 15, I. 29- col. 15, I. 20). The device of Krantz includes: an image detector, disposed to receive summed optical information from an objective lens, illuminated by an illumination system (col. 5, II. 35-60; col. 6, I. 61- col. 7, I. 11; col. 12, I. 54- col. 13, I. 29; Fig. 14; ref. 217); where the objective lens is coupled to the piezoelectric transducer capable of moving the objective lens (Fig. 14; ref. 217). Krantz also teaches using a laser illumination source (ref. 11). Krantz further teaches illumination the specimen region with substantially incoherent light (col. 14, II. 43-62). Krantz teaches the use of micro-lenses (col. 3, II. 17-26; claim 150).
- 23. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscopy of Ohyama in view the illumination and detection means of Krantz. The motivation to modify Ohyama in view of Krantz would have been to provide multi-dimensional imaging using any of the well known devices, including the device as taught by Krantz.
- Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5.680.484) in view of Cheng et al. (USPN 5.909.476).
- 25. The optical imaging microscopy of Ohyama teaches all the limitations of the claimed invention except for expressly teaching that the specimen region comprises an artificially generated test phantom.
- 26. In a similar field of endeavor, Cheng et al. (hereinafter Cheng) teaches simulations done with synthetic noise-free and noisy projection data based on several mathematical phantoms (col. 8. Il. 41-49).

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27. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscopy Ohyama in view of the artificially test phantom of Cheng. The motivation to modify Ohyama in view of Cheng would have been to demonstrate the feasibility of the procedure, as taught by Cheng (col. 8, II. 41-49; col. 9, II. 44-55).

- Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5,680,484) in view of Krantz (USPN 6,248,988) as applied to claim 13 above, and further in view of Short et al. (Pub. No.: 2003/0049841).
- 29. The optical imaging microscopy of Ohyama in view of Krantz teaches all the limitations of the claimed invention except for expressly teaching that the step of acquiring images further includes the step of illuminating the specimen region with an arc lamp.
- 30. In a related field of endeavor, Short et al. (hereinafter Short) teaches capillary based screening for bioactivity (abstract). Short goes on, teaching using an arc lamp illumination source (0255).
- 31. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscopy of Ohyama in view of Krantz with the arc lamp illumination of Short. The motivation to modify Ohyama in view of Krantz with Short would have been to use any known light source including the arc lamp source, as taught by Short.

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 Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5.680.484) in view of Edgar (USPN 4,360.885).

- 33. The optical imaging microscopy of Ohyama teaches all the limitations of the claimed invention except for expressly teaching moving an oil-immersion lens perpendicularly.
- 34. In a related field of endeavor, Edgar teaches micro optical image tomography (abstract). Edgar goes on, teaching moving an oil-immersion lenses to acquire a continuum of focal planes (col. 3, II. 20-22; col. 8, II. 10-40).
- 35. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscopy of Ohyama in view of the movable oil-immersion lens of Edgar. The motivation to modify Ohyama in view of Edgar would have been to use any available known lens including the well-known oil-immersion lens, as taught by Ohyama.
- Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5.680.484) in view of Baer et al. (USPN 5.547.849).
- 37. The optical imaging microscopy of Ohyama teaches all the limitations of the claimed invention including using a tube (ref. 714). However, Ohyama does not expressly teach using a micro-capillary tube.
- 38. In a related field of endeavor, Baer et al. (hereinafter Baer) teaches optical imaging for volumetric capillary cytometery (abstract). Here, Baer teaches the use of a micro-capillary tube (abstract).

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39. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscopy of Ohyama in view the use of a capillary tube of Baer. The motivation to modify Ohyama in view in view of Baer would have been to use any known specimen holder, including the micro-capillary tube of Baer.

- Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Ohyama et al. (USPN 5,680,484) in view of Tsujiuchi et al. (USPN 5,148,502)
- 41. The optical imaging microscopy of Ohyama teaches all the limitations of the claimed invention except for expressly teaching capturing images using an array of collimator fibers wherein each fiber is mapped to a single pixel on a photosensor array.
- 42. In a related field of endeavor, Tsujiuchi et al. (hereinafter Tsujiuchi) teaches an optical image apparatus for producing a plurality of images focused on different planes (abstract). Tsujiuchi also teaches capturing images using an array of collimated fibers wherein each fiber is mapped to a single pixel on a photosensor array, where the array may be a CCD array (col. 17, II. 16-36; col. 18, II. 2-30; col. 42, II. 49-67).
- 43. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscopy of Ohyama in view of the fibers of Tsujiuchi. The motivation to modify Ohyama in view of Tsujiuchi would have been to allow the lens to be distanced from the detector array for use in an endoscope, as taught by Tsujiuchi.

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 Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5.680.484) in view of Rollins et al. (Pub. No.: 2003/0137669).

- 45. The optical imaging microscopy of Ohyama teaches all the limitations of the claimed invention except for expressly teaching capturing images using a microlens array positioned in front of a optical fiber so as to limit acceptance angle, thereby increasing the rejection of scattered light.
- 46. In a related field of endeavor, Rollins et al. (hereinafter Rollins) teaches an optical tomography system comprising: an acousto-optic modulator, which is commonly known to comprise a transducer [abstract; Fig. 15]. Rollins also teaches using a microlens array positioned in front of a optical fiber so as to limit acceptance angle, thereby increasing the rejection of scattered light [0084; pg. 13, Claim B].
- 47. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscopy of Ohyama in view of the microlens and fibers of Rollins. The motivation to modify Ohyama in view of Rollins would have been to allow the lens to be distanced from the detector array for use in an endoscope.
- Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5,680,484) in view of Price et al. (USPN 6,640,014).
- 49. The optical imaging microscopy of Ohyama teaches all the limitations of the claimed invention except for expressly teaching using a coherent fiber bundle.
- In a related field of endeavor, Price et al. (hereinafter Price) teaches a continuous image acquisition and parallel processing in microscopy (abstract). Price also teaches

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volume imaging using coherent fiber bundles attached to a CCD array (col. 2, II. 59-64; col. 3. II. 1-5).

- It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscopy Ohyama in view of the coherent fiber bundle of Price. The motivation to modify Ohyama in view of Price would have been would have been to allow for rapid relative axial adjustment of each of the image faces. as taught by Price et al. (abstract; col. 5, II, 36-61).
- 52 Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5,680,484) in view of Inaba et al. (Pub. No.: 2001/0040094).
- 53. The optical imaging microscopy of Ohyama teaches all the limitations of the claimed invention including maintaining a specimen in a transparent tube (ref. 714). However, Ohyama does not expressly teach that the specimen region comprises a specimen that has been pressure-injected into a micro-capillary tube.
- 54. In a related field of endeavor, Inaba et al. (hereinafter Inaba) teaches capillary tube optical imaging (abstract). Inaba goes on, teaching injection to the inner lumen of the tube a liquid having a particular index of refraction (claim 5).
- 55. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging of Ohyama with the capillary tube containing suspension fluids of particular optical properties of Inaba. The motivation to modify Ohyama in view of Inaba would have been to provide a fluid suspension for the sample using known techniques of capillary fluid injection.

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- Claims 28 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (USPN 5,680,484) in view of Kardos et al. (USPN 6,312,914).
- 57. The optical imaging microscopy of Ohyama teaches all the limitations of the claimed invention except for expressly teaching arranging at least two sets of illumination and image capturing systems in an arc about a specimen region. Ohyama also does not expressly teach the use of colors or dyes.
- 58. In a related field of endeavor, Kardos et al. (hereinafter Kardos) teaches an apparatus for sensitive detection of analytes in microscopy (abstract). Kardos goes on, teaching arranging at least two sets of illumination and image capturing systems in an arc about a specimen region to produce separate images of the specimen (col. 35, II. 36-65; col. 38, II. 20-65; Figs. 1, 4, 28-30). Kardos goes on, teaching the use of dyes to label the specimen where the dyes show unique excitation bands (col. 7, II. 34-64).
- 59. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical imaging microscopy of Ohyama in view of the at least two sets of illumination and image capturing systems arrangement of Kardos. The motivation to modify would have been Ohyama in view of Kardos would have been to simultaneously observe the sample under multiple unique excitations, as taught by Kardos (abstract; col. 6, II. 11-40).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/ Supervisory Patent Examiner, Art Unit 3768